K111911 #1/2

AUG - 4 2011

3. 510(K) SUMMARY

1. Applicant/Sponsor: Corin USA
10500 University Center Drive
Suite 190
Tampa, Florida 33612
Establishment Registration No.: 1056629

2. Contact Person: Lucinda Gerber
Regulatory Affairs Associate
Corin USA
813-977-4469
lucinda.gerber@coringroup.com

3. Proprietary Name: Corin Optimom Modular Head

4. Common Name: Optimom Modular Head

5. Classification Name: 21CFR 888.3360 - Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis

6. Legally Marketed Devices to which Substantial Equivalence is claimed:
   - Corin Unipolar Modular Head (K063791)
   - Corin Taperfit Total Hip System (K003666)
   - Corin Tri-Fit Femoral Stem (K010243)
   - Corin Trinity Acetabular System with HXLPE liners (K110087)

7. Device Description:

The Corin Optimom Modular Head is a polished, truncated sphere with a high tolerance internal female taper. It is a device modification of the internal female taper of the Corin Unipolar Modular Heads (K063791) to provide for compatibility with an additional range of Corin femoral hip stem designs with a 12/14 male taper. The materials and dimensions of the internal female taper are substantially equivalent to the CoCr Modular Heads cleared in K003666 and K010243 and the Trinity Modular Heads cleared in K110087. The Optimom Modular Head is manufactured from Cobalt-Chrome alloy conforming to

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ASTM F75 and is available in diameters ranging from 40-56mm with a variety of offsets.

8. Intended Use / Indications:

The Corin Optimom Modular Head is indicated for hemi-arthroplasty in cemented and uncemented primary or revision femoral stem applications whose indications include procedures for patients suffering pain and disability due to osteoarthritis, rheumatoid arthritis, avascular necrosis of the femoral head, femoral neck fracture and abnormalities where the major pathology affects the femoral head, the acetabular cavity is normal and acetabular replacement is either undesirable or not required.

The device is intended for prescription use only.

9. Summary of Technologies/Substantial Equivalence:

The Optimom Modular Heads have the same intended use and indications as the Corin Unipolar Modular Heads (K063791). The range of diameters available for the Optimom Modular Heads is within the range cleared for the predicate Unipolar Modular Heads and the device design is similar to the Unipolar Heads with the only modification of the internal female taper. The Optimom Modular Heads are manufactured from the same material as the predicates Unipolar Modular Heads, CoCr Modular Heads (K003666, K010243) and Trinity Modular Heads (K110087). The design and dimensions of the internal female taper of the Optimom Modular Heads are the same as the internal female taper of the predicates CoCr Modular Heads and Trinity CoCr Modular heads. Based upon these similarities, the Optimom Modular Heads are believed to be substantially equivalent to the predicate devices.

10. Non-Clinical Testing:

Non-clinical testing conducted to demonstrate substantial equivalence includes a comparison of the designs, materials, intended use, indications and dimensions of the Corin Optimom Modular Head to the predicate devices Fatigue, rotational torque, axial pull off, and fretting corrosion were conducted.

11. Clinical Testing:

Clinical testing was not necessary to determine substantial equivalence between the Corin Optimom Modular Heads and the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Corin USA
% Ms. Lucinda Gerber
Regulatory Affairs Associate
10500 University Center Drive, Suite 190
Tampa, Florida 33612

AUG - 4 2011

Re: K111911
Trade/Device Name: Corin Optimom Modular Head
Regulation Number: 21 CFR 888.3360
Regulation Name: Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis
Regulatory Class: Class II
Product Code: KWL
Dated: July 01, 2011
Received: July 05, 2011

Dear Ms. Gerber:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

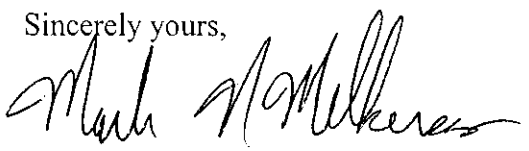
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. INDICATIONS FOR USE

510(k) Number (if known): K111911

Device Name: Corin Optimom Modular Head

Indications for Use:

The Corin Optimom Modular Head is indicated for hemi-arthroplasty in cemented and uncemented primary or revision femoral stem applications whose indications include procedures for patients suffering pain and disability due to osteoarthritis, rheumatoid arthritis, avascular necrosis of the femoral head, femoral neck fracture and abnormalities where the major pathology affects the femoral head, the acetabular cavity is normal and acetabular replacement is either undesirable or not required.

The device is intended for prescription use only.

Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR Over-The-Counter Use (21 CFR 801 Subpart C)	

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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